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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,065	05/05/2005	Hector F Deluca	1256-01012	1544

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EXAMINER	
JAVANMARD, SAHAR	

ART UNIT	PAPER NUMBER
1609	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/509,065	DELUCA ET AL.	
	Examiner	Art Unit	
	SAHAR JAVANMARD	1609	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *06 June 2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Office Action is in response to the 371 of PCT/US03/07443 filed March 12, 2003.

Claims 1-28 are being examined on the merits herein.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefore..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-28 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 1-28 of copending Application No. 10/105,826. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 8-11, 20 and 22, 23, and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Deluca et al. (WO 98/41501) of record.

Applicant claims a method of stimulating osteoblastic-mediated growth of new bone administering an effective amount of compound of formula I (claim 1); wherein the compound is administered orally (claim 2); parenterally (claim3); transdermally (claim 4); topically (claim 5); administered in a dose of 0.01-50 μg per day (claim 8); wherein the mammal is human (claim 9); wherein the compound administered is 2- methylene-19-nor-20(S)- 1α,25-dihydroxyvitamin (claim 10); and its acylated derivative (claim 11); wherein a compound of formula VII is administered (claim 22); compounds of formula I are administered to stimulate healing of a bone fracture (claim 23); and stimulate solidification of an implant in bone (claim 25).

As per claims 1,10, 11, 20 and 22, Deluca discloses compounds of formula I as potential therapeutic agents for the treatment of diseases where bone formation is desired (abstract; page 7, lines 3-10). Since Deluca teaches that they are treating diseases where new bone formation is desired, they are stimulating osteoblastic-mediated growth of new bone inherently.

Deluca further teaches that said compounds can be administered orally, parenterally, transdermally, and topically as recited in claims 2, 3, 4, and 5 respectively (page 7, lines 12-13; also page 34, line 20-page 35, line 10).

Furthermore, as per claim 8, Deluca teaches that said compounds may be administered in doses of 0.1 μg to 50 μg per day (page 7, lines 13-15).

Additionally, Deluca teaches that the compounds of the invention are also especially suited for treatment and prophylaxis of human disorders which are characterized by an imbalance in the immune system, including the improvement of bone fracture healing and improved bone grafts as cited in claims 9, 23, and 25 (page 7, lines 17-24).

Claims 1-5, 8, 9 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Deluca et al. (US Patent No. 5,945,410).

Claims 1-5, 8, and 9 are recited as above. Claim 21 recites administration of compounds of formula VI for use of stimulating osteoblastic-mediated growth of new bone.

Deluca teaches compounds of formula VI (column 2, formula 1) as per claim 1 and 21.

Deluca teaches that these compounds are preferred therapeutic agents for the treatment of diseases where bone formation is desired and provides the methods of administration and dosage regimen as mentioned above, as per claims 1-5, 8 and 9 (column 4, lines 10-20).

Claims 1-5, 8, 9 and 20, and 22-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Deluca et al. (WO 02/05823).

The claimed subject matter is recited above.

Deluca teaches a compound of formula I (page 3) as per claim 1, 20, 22.

Deluca teaches a compound that is a preferred therapeutic agent for the treatment of diseases where bone formation is desired and provides the methods of administration and dosage regimen as mentioned above, as per claims 1-5, 8 and 9 (page 4, lines 1-13).

Additionally, Deluca teaches that the compound is also especially suited for treatment and prophylaxis of human disorders which are characterized by an imbalance in the immune system, including the improvement of bone fracture healing and improved bone grafts as cited in claims 9, 23, 25 (page 4, lines 14-20).

Furthermore, as per claim 24, the reference teaches that this compound increases breaking strength as well as crushing strength and thus could be also used in

conjunction with bone replacement procedures such as hip replacements, knee replacements, and the like (page 5, lines 3-7).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 6, 7 and 11, 12-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deluca (U.S. Patent No. 5,843,928), hereinafter "Deluca (US Patent)", in view of Deluca (WO 97/11053), hereinafter "Deluca (WO)".

Claim 6 recites administering compounds of formula I at sites where new bone growth is desired; in slow release form (claim 7); with acyl ester protected hydroxyl groups (eg, triacetate, trihexanoate, trinonoate, and acetate) as shown in formula in claim 11 (claims 12-19).

Deluca (US Patent) is discussed above. Deluca (US Patent) teaches that Y1, Y2, and R5 can be hydroxyl protected (page 4, lines 11-12). It does not explicitly teach that the protecting groups are acyl esters.

Deluca (WO) teaches that among the modified vitamin D compounds, which may be used where bone formation is desired, having a desirable *in vivo* bioactivity profile, an especially important and preferred class of protecting groups are certain acyl ester derivatives (page 6, lines 26-30). Some specific examples are triacetate, trihexanoate, trinonoate, and acetate, as per claims 12-19 (page 11, line 22-page 12, line 5).

Furthermore, Deluca (WO) teaches that these hydrolysable groups, depending on the type, size, and structural complexity will hydrolyze at different rates in vivo, thus providing for a slow release profile (page 5, lines 1-20).

It would have been obvious to one of the ordinary skill in the art to have protected the compounds taught in Deluca (US Patent) with the protecting groups (e.g. acyl

esters) as taught in Deluca (WO). Furthermore, as evidenced by Deluca (WO), by virtue of having these hydrolysable groups, there will be different rates of hydrolysis in vivo, thereby providing for a slow release profile.

Thus, one would have been motivated to make such a modification in order to achieve an expected benefit of desired bone formation in the subject. The pharmaceutical forms, e.g., slow-release, etc; are deemed obvious since they are all within the knowledge of the ordinary pharmacologist and represent conventional formulations.

Claim 1 and 26-28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Deluca (WO 98/41501) as applied to claims 1-5 and 8-11 above, and further in view of Chin (U.S. Patent No. 5,976,142).

Claim 26 recites where the compound of formula I is administered to stimulate osseointegration of a dental implant; stimulate periodontal bone (claim 27); and administered following a distraction osteogenesis procedure (claim 28).

Deluca (WO) is discussed above.

Deluca (WO) does not teach the active agent to be administered following a distraction osteogenesis procedure.

Chin discloses that distraction osteogenesis refers to a technique for growing

bone or osteogenesis (bone formation) and the procedure desires achieving bone formation (column 1, lines 32-48).

It would have been obvious to one of ordinary skill in the art to administer the active agent taught by Deluca (WO) following a distraction of osteogenesis procedure because Deluca (WO) teaches that the active agent is useful for the bone formation and bone formation is a desired outcome of distraction osteogenesis procedure as disclosed by Chin. Furthermore, Chin teaches that as the gap between the bone segments widens, the body's own natural healing capacity fills the void with new bone and adjacent soft tissue (ie, periodontal bone). Once the desired bone formation is achieved, the area is allowed to heal and consolidate (column 1, lines 41-47).

Thus, one would have been motivated to make such a modification in order to expedite the beneficial effect of achieving the desired outcome of achieve bone formation or bone growth by administering the active agent taught by Deluca (WO).

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAHAR JAVANMARD whose telephone number is (571) 270-3280. The examiner can normally be reached on 8 AM-5 PM MON-FRI (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JEFFREY STUCKER can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SJ

MICHAEL MELLER
PRIMARY EXAMINER